endTB Clinical Trial
Treatment during pregnancy Consent Form

Subject Identification

Version 3.3 Version Date: 14 February 2019

Protocol Title: endTB (Evaluating Newly approved Drugs for multidrug-resistant TB)

Sponsor: Médecins Sans Frontières (Doctors Without Borders) - France

Principal Investigators: Carole Mitnick, Sc.D. and Lorenzo Guglielmetti, M.D.

Site Principal Investigator: [Insert PI Name]

Research Center: [Insert Research Center Name]

Participant Name (please print): _____

Study Subject ID: _____

About this consent form

We are asking you to read this form because you are currently receiving study drugs to treat your tuberculosis ("TB") as part of the research study endTB clinical trial, you are at least 18 years of age, and because you are now pregnant. Please read this form carefully. The purpose of this form is to request your consent to continue participating in the study. A member of the research team will also explain to you verbally the information provided in this form.

When you initially consented to participate into the study, we explained that we don't know if some of the medications given in the study are safe if taken during pregnancy. We explained that pregnant women cannot enter the study and we asked you to use birth control while taking the study drugs.

After the _____ dose of the study treatment _____, but before treatment was complete, we learned that you are pregnant. Your study doctor believes that there are more benefits than risks for you to be in the study. Since your condition has changed, we are asking again if you are still willing to participate in the study.

If you have any questions about the information provided, the reason we are asking for your consent or about this form, please ask us. Signing this form is voluntary; it is up to you to decide whether you will stay in the study and keep receiving the study drugs without terminating the pregnancy. If you agree, we will ask you to sign this form to confirm that you want continue. We will give you a signed copy of this form to keep. You can decide to stop taking part in this study at any time if you do not want to, even after signing this form.

If you are not able to sign the consent form, but you would like to participate, you can ask someone you know to sign for you and you can make a thumbprint to show that you understand and would like to continue taking part.

Why is it proposed that I stay in the study even though I'm pregnant?

The effects of your study medications on pregnancy and on the developing fetus (baby still in the womb) are currently not known or not fully understood.

However, based on the information now available about your clinical condition, the drugs you are taking, and your treatment options if you elect another option, your study doctor believes that the expected benefits of continuing to receive the study medications are bigger than the risks for you and your baby.

Will I be told why the doctor thinks I should stay in the study?

Based on the TB study medications you are currently taking and your clinical condition, your study doctor will explain you why s/he has proposed that you stay in the study.
In detail s/he will explain all the options available to you, and:

- the available information about the safety of taking these drugs during pregnancy;
- the possible risks and benefits to you and your baby if you stay in the study;
- the possible risks and benefits to you and your baby if you leave the study;
- the possible (treatment) options you might have if you leave the study; and
- the possible risks to you and your baby from your TB disease if you decide to stop taking TB treatment completely.

If the explanation is not clear, we want you to ask questions until everything is clear and you have sufficient information and time to take your decision.

What will happen during the study, if I decide to remain in the study?

You will be monitored to follow your TB using the same schedule you agreed to when you signed the original research consent form for endTB clinical trial.

If you decide to stay in the study, your study doctor will talk to you, and, if you permit, your gynaecologist and/or obstetrician (doctor in charge of pregnant women), to make sure the development of your baby is closely followed during the whole pregnancy.

We would also like to collect medical information about your pregnancy and the birth and health of your baby. We want to follow you and your baby during the pregnancy and until delivery to try to learn if the study medications have any effect on your pregnancy. We would like to follow the health of your baby at least at 6 and 12 months of age for any important medical issues.

What are the possible risks of staying in the study?

Your study doctor will explain the risks of the treatment for yourself, your pregnancy, your fetus and/or your future baby and you will be given a document entitled "participant information leaflet– pregnant patient" that summarizes the main side effects. The information about these risks is very limited; any known risks of abnormality will be described by your study doctor.

All the other risks (side effects) were explained to you when taking your consent for participation in the research study.

Your privacy will be protected as detailed in the research consent form you have already signed.

Are there benefits to staying in the study?

If your study doctor proposes that you stay in the study, s/he believes that the possible benefits of staying in the study and receiving the study treatment are bigger than the risks for you and your baby.

You will receive greater TB treatment support from the study team than during regular MDR-TB treatment and your pregnancy will be closely monitored.

Others with MDR-TB may benefit in the future from what we learn in this study**.** We hope that the information we gather about your pregnancy while taking the study drugs and after will help future patients and their children by increasing what we know about the possible of the study medications on pregnant women and developing babies.

What should I do if I want to stop taking part in the study?

If you decide you want to stop participating into this study, you should tell us. We will make sure you stop the study safely and we will invite you to make additional study visit(s) called "termination visit" and follow-up visits, as outlined into the research consent form you have already signed.

We will tell you if, at any time, we learn any new information that could make you change your mind and choose to leave the study.

If you decide to stop participating in the study, the study doctor will ask you for permission to collect information about the continuation and the outcome of your pregnancy, and the condition of your newborn (at least at 6 and 12 months of age for any important medical issues).

Information collected from you will be used to help answer study questions. When you leave the study, your information previously collected will still be used and stored during 20 years for the study and future TB research. However, if you prefer this information not to be used and destroyed, you can contact your study doctor or the email address endTB.clinicaltrial@paris.msf.org.

Also, your study doctor, at any point in time after your consent, might ask you to leave the study before you finish it. This may happen for example if s/he thinks that the risks of staying in the study are becoming higher than the expected benefits, or if s/he thinks that you need to receive treatment not allowed by the research study. If this happens, your study doctor will explain in detail all the reasons for his/her decision.

Will I be paid or have to pay additional expenses if I stay in this research study?

You will not receive reimbursements in addition to the ones you already receive for taking part into the study. This study will not cover any costs from your pregnancy, delivery or care of your baby *[to be adapted locally]*. There will be no cost [or payment] to you if you stay in the study.

What happens if my baby is injured or I am injured as a result of taking part in this research study?

The sponsor will pay for costs related to any injury to you,[or any miscarriage or damage to the fetus or your baby] that result from taking part in this study.

If you have a physical injury or you feel your pregnancy might be at risk because of participation in this study, please tell your study doctor and seek medical attention right away; the study team will make sure that you receive appropriate medical treatment and that your pregnancy course is closely monitored.

In an emergency, the study sponsor has made plans to pay for your visit to see a specialist, any related treatment, and/or your stay in the hospital. For non-urgent situations, the sponsor might pay for your visit to see a specialist. The study team will review your situation and decide whether the sponsor will pay for the resulting treatment if your condition is not the result of your participation in the study. You do not waive any of your legal rights by signing this consent form.

Who can I speak to if I have questions, concerns or complaints?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

[PI Name and title] is the person in charge of this research study. You can call him/her at [PI telephone number]. You can also call [Clinical Investigator] at [CI number] with questions about this research study. If you have questions about the scheduling of appointments, call [Study Coordinator] at [SC number].

If you want to speak with someone not directly involved in this research study, please contact the [Research Center IRB] office. You can call them at [Research Center IRB number].

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Informed Consent and Authorization

Your signature on this document means the following:

I have read this consent form. It has been explained to me why I'm being asked to sign this informed consent, the risks and the possible benefits for the fetus and for me resulting from staying in the study. I have had the opportunity to ask questions. I understand the information given to me. I recognize that my participation is voluntary and that I can refuse or end my participation at any time, without any loss of benefits that I would otherwise have. I recognize that by signing this document, I do not lose any of my legal rights as a study participant.

I will receive a complete, signed, dated copy of this informed consent form.

By signing below, I freely agree to continue my participation to the endTB clinical trial and I agree to take the treatments that will be prescribed to me.

Signature of Pregnant Participant

_____ _____ _____

Signature or thumbprint of pregnant participant Date (DD/MMM/YYYY) Time

_____

Name of pregnant participant, printed in capital letters

Witness (if applicable):

_____ _____ _____

Signature of witness Date (DD/MMM/YYYY) Time

_____

Name of witness, printed in capital letters

Study representative who obtained informed consent:

I have explained to the pregnant participant why we are proposing that she continue to participate in the study and the risks for herself and the fetus deriving from the drugs intake and have answered all of her questions. She understands the information described in this document and accepts voluntarily to keep participating in the study.

_____ _____ _____

Signature of representative Date (DD/MMM/YYYY) Time

_____

Name of study representative, printed in capital letters